

REMARKS/ARGUMENTS

Entry of the foregoing and reexamination and reconsideration of the claims as amended are respectfully requested.

The office action indicates that claims 2, 25 and 29 have been rejected, and that claims 1, 3-24, 26-28, 30 and 32-53 have been withdrawn from further consideration as being directed to a non-elected invention. In a prior amendment filed April 13, 2007, applicants explained that they were re-presenting the originally elected subject matter of Group II, i.e., claims 2, 25, 27, 29 and 31. Also by way of that amendment, claim 31 was cancelled and replaced with new claim 53. Thus, it would appear that the Patent Office would have acted consistently and examined claims 2, 25, 27, 29 and 53 on the merits. Yet there is no explanation on the record as to why claims 27 and 53 have been grouped with the withdrawn claims. Accordingly, applicants respectfully request the examiner to group claims 27 and 53 with the elected invention. Applicants will now address the sole outstanding issue with the belief that it was intended to include claims 2, 25, 27, 29 and 53.

Claims 2, 25, 27, 29, and 53 are amended hereby and claims 54 and 55 are added hereby. No new matter has been introduced. The amendments to claim 2 generally are typographical. The term "alkyl" in claim 2 has been corrected to acyl to reflect the fact that component B is a fatty acid derivative. Claims 25 and 27 were amended to recite cyclosporins or taxanes, respectively, generically, and the specifically recited species have been moved to new claims 54 and 55. These amendments need no further support than the original claims 25 and 27. Similarly, claim 29 has been amended to correct its syntax.

Claims 2, 25 and 27 have been rejected under 35 U.S.C. § 103 as being unpatentable over Stuchlik, WO 98/10747 (hereinafter "Stuchlik"). The office action alleges that

Stuchlik discloses, in page 4, compositions comprising cyclosporine and polyglycerol esters, but not the specific ratios of components. While the latter statement is true, it is, by no means, the only difference. A determination has been made that it is within the capability of the ordinarily skilled drug formulation specialist to vary dosages in order to achieve a target pharmacokinetic objective, thus rendering the claims obvious. Applicants disagree with the determination reached by the Patent Office, as that determination would be applied to the claims as amended.

Stuchlik teaches a cyclosporin formulation containing as component (b) polyglycerol esters of fatty acids and fatty acid derivatives such as thereof formula (1). This is optional as it is only one possible component (b) according to Stuchlik. This formula is very general and broad in scope. Compounds containing up to 16 glyceryl units and a wide range of saturated and unsaturated C18-C22 fatty acids or hydroxylated fatty acids or mixtures thereof are encompassed within this disclosure. An extremely large number of compounds are covered, having a correspondingly extremely large number of individual HLB values. Since R can be H or a long alkyl chain, individual compounds embraced by the prior art formula can be relatively lipophilic or hydrophilic in character. Many of these compounds will have HLB values of less than 10. For example the first 5 esters listed in the middle of page 9 of the specification have HLB values less than 10, whereas the last 4 esters in this list have HLB values greater than 10. Moreover, nothing in Stuchlik limits the use of a polyglycerol ester where at least one R group is not H.

And contrary to the allegations stated in the office action, Stuchlik does not teach use of a mixture of two polyglyceryl esters, one having an HLB value not greater than 9 and the other having an HLB value not less than 10. Stuchlik does not specifically disclose use of a polyglyceryl-3 ester of

oleic acid having an HLB value of not greater than 9. Thus, there is no scientific rationale by which a skilled person would have arrived at the claimed compositions, primarily on the basis of the teachings in Stuchlik. Indeed, with no guidance from Stuchlik regarding these many issues including, without limit, the need to use both one component with an HLB over 10 and another which is under 9, the use of a polyglycerol fatty ester with at least one group that is not H, and the use of polyglycerol-3-esters of oleic acid, arriving at the present invention, would be an exercise in sheer serendipity.

On the basis of the foregoing, reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above, each of the presently pending elected claims 2, 25, 27, 29 and 53, as well as newly added claims 54 and 55, is believed to be in immediate condition for allowance. Accordingly, the examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

If, however, for any reason the examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

By


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